



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/937,905

10/01/2001

Shiken Sha

0230-0169P

5513

2292 7590 01/30/2007
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

KEMMERER, ELIZABETH

ART UNIT

PAPER NUMBER

1646

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
--	-------------------	---------------

3 MONTHS

01/30/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/30/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

09/937,905

Applicant(s)

SHA ET AL.

Examiner

Elizabeth C. Kemmerer, Ph.D.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5, 6, 9, 11, 12, 18-21, 24, 29, 31 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 6, 9, 11, 12, 18-21, 24, 29, 31, and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment and terminal disclaimer received 13 November 2006 has been entered in full. The terminal disclaimer has been approved and recorded.

Claims 3, 4, 7, 8, 10, 13-17, 22, 23, 25-28, 30, and 32 are canceled. Claims 1, 2, 5, 6, 9, 11, 12, 18-21, 24, 29, 31, and 33-37 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The provisional rejection of claims 1, 2, 5, 6, 9, 11, 12, 18-21, 24, 29, 31, and 33-35 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent Application No. 10/381,710 as set forth at pp. 8-9 of the previous Office Action (mailed 13 June 2006) is *withdrawn* in view of the terminal disclaimer received 13 November 2006, which has been approved and recorded.

The rejection of claims 21 and 24 under 35 U.S.C. § 112, first paragraph, for complete lack of enablement as set forth at pp. 6-8 of the previous Office Action (mailed 13 June 2006) is *withdrawn in part* in view of the amended claims (submitted with the amendment received 13 November 2006). See section on 35 U.S.C. § 112, first paragraph, below for remaining enablement issues regarding these claims.

The rejection of claims 1, 2, 5, 6, 9, 11, 12, 18-20, 29, 31, and 33-35 under 35 U.S.C. § 112, first paragraph, for scope of enablement as set forth at pp. 3-6 of the previous Office Action (mailed 13 June 2006) is *withdrawn in part* in view of the amended claims (submitted with the amendment received 13 November 2006). See section on 35 U.S.C. § 112, first paragraph, below for remaining enablement issues regarding these claims.

35 U.S.C. § 112, First Paragraph

Claims 1, 2, 5, 6, 9, 11, 12, 18-21, 24, 29, 31, 33-35, and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed invention wherein the recited protein comprises a sequence at least 95% identical (through conservative amino acid substitution) to the extracellular domain or full-length sequence of SEQ ID NO: 2 wherein the protein binds the antibody produced by a hybridoma of the cell line deposited as FERM BP-6103, does not reasonably provide enablement for the invention as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is essentially the same as that set forth at pp. 3-6 of the previous Office Action (mailed 13 June 2006). However, in view of Applicant's arguments and upon further consideration, a small number of variants is also deemed enabled, as defined above.

Applicant's arguments (pp. 7-8, amendment received 13 November 2006) have been fully considered but are not found to be persuasive for the following reasons. Specifically, Applicant argues that the references relied upon by the examiner predate the invention by at least 5-10 years. Applicant urges that the field of molecular biology advanced dramatically in that time. This has been fully considered but is not found to be persuasive. Admittedly, all fields of research progress, however, no evidence has been submitted to support that the advancements in this field over the time period in question was so dramatic that the references are no longer applicable. Arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).

Applicant further argues that a person skilled in the art would readily be able to screen variants of proteins having 90% sequence identity for the required activity. This has been fully considered but is not found to be persuasive. Again, no evidence has been brought forth to support the contention that 90% is an appropriate cut-off for predictability. The examiner concedes that protein of at least 95% identity as defined

Art Unit: 1646

above would be enabled, as such is consistent with the guidelines set forth in the M.P.E.P. and the utility guidelines available at the USPTO's web page.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The basis for this rejection is essentially the same as that set forth in the rejection of claims 21 and 24 at pp. 6-8 of the previous Office Action (mailed 13 June 2006), since new claim 36 relies upon the recited receptor having the activity of producing G-CSF.

Applicant's arguments regarding this issue appear to be limited to a discussion of how claim 21 was amended to obviate the rejection. The argument was persuasive as it pertained to claim 21. However, new claim 36 has the same issue.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 2, and 9 of this application conflict with claims 1, 2, and 9 of Application No. 10/381,710. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 1, 2, and 9 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, and 9 of copending Application No. 10/381,710. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1646

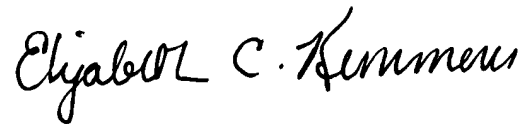
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ECK



ELIZABETH KEMMERER
PRIMARY EXAMINER